

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

EXELIXIS, INC.,

Plaintiff,

v.

MSN LABORATORIES PRIVATE LIMITED  
and MSN PHARMACEUTICALS, INC.,

Defendants.

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) C.A. No. 19-2017 (RGA) (SRF)  
) **CONSOLIDATED**  
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**OPPOSITION LETTER TO THE HONORABLE SHERRY R. FALLON  
REGARDING THE PROTECTIVE ORDER DISPUTE**

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Dear Judge Fallon:

We write in response to Exelixis's letter seeking an order preventing MSN employee Dr. Kondal Reddy Bairy from accessing Exelixis's Confidential Information under the Protective Order entered in this case. This request, if granted, would cripple MSN's right to fully and effectively defend itself because [REDACTED]. Exelixis's arguments do not justify such extraordinary relief or its prejudicial effect on MSN.

Exelixis first argues that Dr. Bairy should not have access to Confidential Information under the terms of the Protective Order because he is not an attorney. But the Order expressly differentiates between in-house attorneys and other legal department personnel, giving *both* types of employees performing a legal function for a party in litigation access. [REDACTED]

[REDACTED] Exelixis's contrary interpretation makes no sense because [REDACTED]. The Order should not be interpreted to permit *two* in-house personnel from Exelixis to have access to MSN Confidential Information, [REDACTED].

Exelixis's other argument is that Dr. Bairy should not be permitted access to Confidential Information because he is purportedly involved in so-called "competitive decision-making." But Exelixis's argument is based solely on speculation about Dr. Bairy's roles at MSN. His sworn deposition testimony and attached declaration confirm [REDACTED]

[REDACTED] (See Ex. 1.) Even if Dr. Bairy did have some relevant competitive decision-making role, Exelixis's argument fails, because nothing in the Protective Order precludes access to designees that are competitive decision makers, researchers, product developers, or regulatory agents. The only restriction the Order places on a designee's job responsibilities is that they may not prosecute patents related to the product at [REDACTED]. The parties addressed all other concerns about disclosure of Confidential Information by including a broad bar on the "use" of information for any purpose other than the conduct of this litigation. Dr. Bairy has signed the Order and will abide by that restriction, which should end the dispute.

Exelixis cannot identify any harm that could reasonably result from the "attenuated risk of competitive misuse" raised by their letter. See, e.g., *Xerox Corp. v. Google, Inc.*, 270 F.R.D. 182, 185 (D. Del. 2010). The far more real harm is the prejudice MSN would suffer if Exelixis's request is granted.

**I. Dr. Bairy [REDACTED] and Should Be Granted Access to Confidential Information under the Protective Order.**

Exelixis argues that "MSN has already agreed to a protective order that expressly limits the categories of qualified individuals to lawyers." (D.I. 157, Exelixis's Letter ("Ltr.") at 3.) That is incorrect. The Protective Order states that two "in-house attorneys or legal department personnel" may receive Confidential Information. (Ex. 2, ¶ 11.B.) [REDACTED]



[REDACTED]

Exelixis notes that Dr. Bairy serves another role [REDACTED], but this is irrelevant under the terms of the Protective Order, which provides access to legal department personnel.

Exelixis's "attorneys only" interpretation is also irreconcilable with the fact that [REDACTED]. Certainly, MSN did not believe it was agreeing to an order that would categorically bar anyone at MSN from accessing Confidential Information or being fully informed and involved with the defense of this case. (*Id.* ¶ 4.) At best, Exelixis's reading of the "legal department personnel" language improperly elevates form over substance, because Exelixis does not and cannot articulate why there is a generally heightened risk of misuse solely by virtue of someone being a non-attorney. That is why providing confidential access to non-attorneys is commonplace in this District, particularly in Hatch-Waxman cases. (*See, e.g.*, Ex. 3, ¶ 2.6; Ex. 4, Tr. at 11:22-12:13.)

Indeed, Judge Norieka recently addressed the same situation in which a Hatch-Waxman plaintiff tried to prevent any MSN employee from accessing its confidential information. (*See* Ex. 4 Tr. at 5:5-8, 11:22-12:13.) The Court rejected that request and ruled that "because [MSN] ha[s] no in-house counsel, and by definition would have no one who could see any confidential information, I will allow them to have one person who is not an attorney have access under the protective order." (*Id.*) Exelixis notes that Judge Norieka required that the MSN designee could not have responsibilities for research and development, but Dr. Bairy has no such responsibilities, as discussed below. Finally, Exelixis asks this Court to depart from Judge Norieka's recent decision and, essentially, require [REDACTED], as much larger generic companies like Teva have done. No doubt Exelixis and branded pharmaceutical companies would benefit if such a barrier to entry for smaller generic competitors were erected for Hatch-Waxman litigation in this District. But that is not what the law or the Protective Order requires. This Court should decline Exelixis's remarkable request and permit access to Dr. Bairy as MSN's legal department personnel under the terms of the Protective Order.

## **II. There is Good Cause to Permit Disclosure to Dr. Bairy Because [REDACTED]**

Even if the Court deems that amendment of the Protective Order's "attorneys or legal department personnel" provision is necessary for Dr. Bairy to gain access to Confidential Information, then ample good cause supports that change. Exelixis's only argument against amendment is its generalized concern that Confidential Information is at a heightened risk of disclosure in Dr. Bairy's hands because he is allegedly involved in "competitive decision-making."

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<sup>1</sup> Black's Law Dictionary broadly defines "legal" as "Of or relating to law; falling within the province of law." *Legal*, Black's Law Dictionary (11th ed. 2019).

As an initial matter, this argument fails because the Protective Order contains *no bar* to access by so-called competitive decision-makers. Its only restrictions on duties an employee with access can perform is a bar on prosecuting patents related to cabozantinib (Ex. 2, ¶ 11.A), which [REDACTED] (Ex. 1, ¶ 9), and a *use* bar that restricts those with access from improperly *using* the information for purposes like “research, development, manufacture, patent prosecution, financial, commercial, marketing, regulatory, business, or other competitive purpose.” (Ex. 2, ¶ 10.) As with every other individual who has signed the Protective Order, including in-house counsel and the 13 experts disclosed by Exelixis, Dr. Bairy has affirmed he will not use the information in any of those prohibited ways. (Ex. 1, ¶ 1.)

Even if the Protective Order barred competitive decision-makers from accessing Confidential Information, [REDACTED]

(Ex. 1, ¶ 6.) Exelixis makes a series of vague statements that [REDACTED]

But the Federal Circuit has held, when evaluating who is a competitive decision-maker, “the standard is not ‘regular contact’ with other corporate officials who make ‘policy,’ or even competitive decisions, but ‘advice and participation’ in ‘competitive decision-making.’” *Matsushita Elec. Indus. Co. v. United States*, 929 F.2d 1577, 1579-80 (Fed. Cir. 1991) (reversing denial of access). [REDACTED]; *See Intel Corp. v. VIA Tech., Inc.*, 198 F.R.D. 525, 529 (N.D.Cal. 2000) (“[U]nrebutted statements” that one “does not participate in competitive decisionmaking, which the court has no reason to doubt, form a reasonable basis to conclude” that one is “isolated from competitive decisionmaking.”)

[REDACTED] and Exelixis does not argue otherwise.

The most Exelixis can say is that Dr. Bairy has a Ph.D. in synthetic chemistry and [REDACTED]

[REDACTED] (Ex. 1, ¶ 8.) Exelixis has provided no evidence—only vague speculation—that Dr. Bairy is in a position to misuse Confidential Information as part of the regulatory approval process for the ANDA at issue. For



example, Exelixis asserts that [REDACTED]

Dr. Bairy's roles at MSN stand in stark contrast to those of the competitive decision-makers in the cases cited by Exelixis. In *Safe Flight Instrument Corp. v. Sundstrand Data Control Inc.*, the court denied access to the patentee's president, who was also the inventor on over 60 patents and a working engineer actively involved in research and development. 682 F.Supp. 20, 21-22 (D. Del. 1988). In *R.R. Donnelley & Sons Co. v. Quark, Inc.*, the court denied access to the plaintiff's "President of Corporate Strategic Initiatives," whose responsibilities included advising the plaintiff "on company-wide business initiatives and opportunities for growth," and serving a supervisory role in the company's "research and development and applications engineering and other strategic initiatives." 2007 WL 61885, at \*1 (D. Del. Jan. 4, 2007). Yet the same court permitted access to a "Chief Patent Counsel" that "supervised the legal decision-making related to [patentee]'s intellectual property portfolio and its enforcement" and stated that "the risk of inadvertent disclosure" can be overcome if "*in-house counsel's lack of access would impede a party's ability to litigate through outside counsel.*" *Id.* (emphasis added).

Exelixis has also failed to identify "any greater possibility of abuse of the confidential information" due to Dr. Bairy's role at MSN that differs from the risk that might exist with in-house counsel or outside consultants or experts. *E.I. duPont de Nemours & Co. v. Phillips Petroleum Co.*, No. 81-508, 1982 WL 63780, at \*2 (D. Del. May 17, 1982). Judge Norieka recently agreed that any risk of misuse could be sufficiently minimized so long as the designated MSN employee would "abid[e] under the protective order and submit to the jurisdiction of the court for any breach of the protective order." (Ex. 4 at 8:1-11, 12:6-13.) *see also Ecix Corp. v. Exabyte Corp.*, 95 F. Supp. 2d 1155, 1159 (D. Colo. 2000) (permitting CFO to attend depositions with protected information where the protective order only permitted attorneys and experts to have access so long as the CFO abided by the protective order); *Bailey v. Dart Container Corp. of Michigan*, 980 F. Supp. 560, 583 (D. Mass.), *on reconsideration in part*, 980 F. Supp. 584 (D. Mass. 1997) (allowing competitor's in-house product development expert access to patentee's confidential information because "agreeing to be bound by the terms of the [protective] order sufficiently protects [patentee]'s interests"). Dr. Bairy agreed to those terms when he signed the Confidentiality Undertaking required by the Protective Order.

With the safeguards provided by the Protective Order, the minimized risk of any potential misuse is far outweighed by the prejudice to MSN of [REDACTED]. *Brit. Telecommunications PLC v. IAC/InterActiveCorp*, 330 F.R.D. 387, 391 (D. Del. 2019) ("The Court must then balance that risk against the prejudice."). "The general possibility of the unintentional use of confidential information in subsequent FDA-or patent-related proceedings is insufficient to overcome the real prejudice that" MSN would suffer. *Vivus, Inc. v. Actavis Lab'ys FL, Inc.*, No. 14CV3786SRCCLW, 2016 WL 590212, at \*5 (D.N.J. Feb. 11, 2016). MSN respectfully requests that the Court deny Exelixis's request to preclude Dr. Bairy from access to Confidential Information under the Protective Order.

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Dated: July 9, 2021

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